April 2, 1986

Dear Manufacturer: CD-86-06 (LD)

Subject: Compliance with Sections 202(a)(4) and 206(a)(3) of the Clean Air Act

On August 16, 1985, EPA sent the enclosed letter to Volkswagen of America, Inc. (Volkswagen) conditionally approving its request to use a manganese fuel additive for particulate trap regeneration for its light-duty diesel vehicles. This letter gave approval for Volkswagen to use this additive for the 1986-1988 model years. EPA's temporary approval of this additive's use was based on the fact that its use only by Volkswagen in its diesel vehicles (a small portion of the in-use fleet over the next few years) will have a negligible impact on current ambient manganese levels. This letter states, however, that until Volkswagen can provide EPA with conclusive data on the long term health risks at various projected ambient levels, EPA cannot grant permanent approval under current policy and statute. The enclosed letter to Volkswagen is provided as an example of how EPA will address any similar requests by manufacturers in the future.

Advisory Circular Nos. 76 and 76-1 (Subject: Compliance with the Requirements of Sections 202(a)(4) and 206(a)(3) of the Clean Air Act) provide background on EPA's policy in addressing Volkswagen's request or other similar requests involving currently unregulated pollutants. The language of Sections 202(a)(4) and 206(a)(3) taken together make it clear that it is the manufacturer's responsibility to provide sufficient evidence that an emission control system will not cause or contribute to an unreasonable risk to public health, welfare or safety.

On March 20, 1984, EPA sent a letter to all manufacturers concerning clarification of the role of the Health Effects Institute (HEI) with regard to Section 202(a)(4). This letter indicated that EPA will accept conclusive data from health effects projects sponsored by the HEI as satisfying the health testing requirements of this section. Also the letter indicated that manufacturers must submit needs requests to HEI;

the needs should clearly specify the health effects research which the manufacturer deems most important. Additionally, these needs requests should be submitted sufficiently in advance so that needed health data can be obtained in time for both the manufacturer and EPA to assess any health problems prior to manufacturers' decisions on commercialization of a new technology. Use of HEI to provide conclusive health data to EPA is not required however. Manufacturers may, of course, submit health data independent of work done by HEI.

Finally, data which provides conclusive evidence of the health risks associated with an emission control system (either presented through HEI for the manufacturer or by the manufacturer independent of HEI) satisfies only part of the requirements of Sections 202(a)(4) and 206(a)(3). An example of the type of information needed (and is not satisfied by HEI work) is emission characterization tests to identify unregulated emissions from vehicles or engines being certified. Such characterization testing is part of the manufacturers' statutory responsibility to assure that emission control devices, systems, or elements of design in new motor vehicles or engines do not cause or contribute to an unreasonable risk to public health, welfare, or safety. Thus, besides its responsibilities relative to health risk assessment of the use of a manganese fuel additive, Volkswagen, for example, must submit detailed information which characterizes the resulting exhaust emissions. Specifically, Volkswagen must identify the chemical forms and respective quantities of each form of manganese emitted. Detailed research plans and time schedules to be followed in acquiring this information must also be submitted to EPA by Volkswagen.

I hope you find this information useful. Please advise if you have any questions.

Sincerely yours,

Robert E. Maxwell, Director
Certification Division
Office of Mobile Sources

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ANN ARBOR, MICHIGAN 48105

Mr. Wolfgang Groth, Manager
Emissions Certification & Fuel Economy
Volkswagen of America, Inc.
293 East Liberty Plaza
P.O. Box 7050
Ann Arbor, MI 48107

Dear Mr. Groth:

Subject: Manganese Fuel Additive-Based Particulate Trap Regeneration System

This letter responds to your August 23, 1984 request to certify 1986 and later model year vehicles using a manganese fuel additive for diesel particulate trap regeneration. Based on the information you have supplied, we have concluded the use of this system for the interim period of 1986 through 1988 model years would not pose an unreasonable risk to public health, welfare, or safety.

We are approving this on a limited basis because no studies have yet been conducted that address the potential harmful effects of manganese at the low ambient concentrations that would likely result from its use. For example, your worst-case dispersion model projects potential street canyon concentrations of manganese at 7.6 Ug/m3 if all vehicles were diesel and all used the manganese system, and if all manganese introduced to the system were emitted. In reality, however, the concentrations will be lower as a portion (at least 30 percent based on California Air Resources Board CARB) data) of the manganese is retained on the particle filter and only a fraction (presently about 3% of new car sales) of the vehicle population is diesel-powered. Furthermore, it would take several years for fleet turnover to occur. Therefore, actual concentrations could be more on the order of 0.14 Ug/m3 in street canyons after fleet stabilization. (Note: This assumes a future fleet portion of 3 percent diesel vehicles, all equipped with the manganese additive.)

This level far exceeds the 1982 manganese concentration of urban areas of 0.033 Ug/m3 as measured by the National Air Surveillance Network, but it is far below any levels that have been used to determine adverse human health effects.

We have been in contact with representatives of Lubrizol Corporation. They have supplied copies of studies outlining Lubrizol 8220 oral toxicity, primary skin irritation, and primary eye irritation in animals. Results indicate that Lubrizol 8220 is not toxic in rats in tests by the oral route of administration and is not a primary skin irritant to rabbits. Lubrizol 8220 is, however, a possible primary eye irritant, based on a study using rabbits. A material safety data sheet supplied by Lubrizol states that "inhalation may cause respiratory irritation, dizziness, nausea and headache." These effects occur at higher exposure levels and it is not known with certainty what effects would occur at lower exposure levels to the additive or, more importantly, exhaust emission products from combustion of this additive. We are not aware of any inhalation studies in animals or threshold limit value established for humans for this product or its combustion products.

The Fraunhofer Institute report1 which you have supplied amplifies the lack of information that exists in regard to Lubrizol in diesel trap oxidizers. The report states, "To date, no study is available giving a toxicological evaluation of Lubrizol. As expected under these circumstances, there is also no threshold limit value (TLV) announced for this Mn compound."2 The report also states, "There are no studies available ,n the toxicity of Lubrizol 8220 or its combustion products."3

However, EPA has recently released a health assessment document for manganese in which the key health effects studies of manganese and manganese compounds have been summarized and evaluated. The key health effects of manganese are in the central nervous system and the lungs. Adverse, irreversible effects to the central nervous system result from chronic manganese poisoning, known as manganism. Exposure to levels as low as 1 mg/m3 have been associated with these effects. There is little supportive animal data.

Our temporary approval of the use of this system stems from the fact that one use of the system, in a small portion of the in-use fleet over the next few years, will have a negligible

1. Fraunhofer-Institut fuer Toxikologie and Aerosolfurschung Institutsteil Hannover/Muenster, Evaluation of Health Effects Associated with the use of a Manganese Additive in Connection with the Diesel Trap Oxidizer Reqeneration, Under Contract to Volkswagenwerk AG. Feb. 1984.

2. Ibid., p. 23.

3. Ibid., p. 25.

impact on current ambient manganese levels. As such, until Volkswagen can provide EPA with conclusive data on the long term health risks at various projected ambient levels, EPA cannot grant permanent approval under current policy and statute.

Our policy in this matter is outlined by Advisory Circular Nos. 76 and 76-1 (Subject: Compliance with the Requirements of Sections 202(a)(4) and 206(a)(3) of the Clean Air Act). The language of Sections 202(a)(4) and 206(a)(3) taken together make it clear that the burden is on the manufacturer to make the requisite showing that the emission control system will not cause or contribute to an unreasonable risk to public health, welfare or safety.

The finding of unreasonable risk requires a number of trade-offs. First, Section 202(a)(4)(B) explicitly indicates that relevant information on health effects of diesel particulates be considered. In other words, consideration of trade-offs between diesel particulate control and control of other unregulated pollutants is appropriate. There must be a comparative analysis of alternative competing technologies. There also has to be a "comparison among unregulated pollutant risks" and then a "balancing" of these factors.

The use of the words "cause or contribute" suggests that more is required than merely a showing that emissions of VW/Audi unregulated pollutants do not create an unreasonable risk. If, for example, there were the potential for an unreasonable risk posed by ambient concentrations of manganese from a number of sources, then any emissions increase could be found to contribute to that unreasonable risk. Again, whether a risk is unreasonable turns on a balancing of technological and health effects factors.

Considering the balancing of the technological and potential health effects, we have decided not to refuse initial certification of a potentially promising particulate control technology at this early stage. However, it is Volkswagen's responsibility to assure the necessary research is conducted.

EPA will not authorize the certification of vehicles using manganese additives beyond the 1988 model year unless significant progress is made in conducting the research. We would expect the entire issue should be resolved in time to decide on a control strategy for the 1990 and later model years. To this end, Volkswagen should submit a detailed research plan to EPA by late this year or early next year. The plan should discuss all relevant health work in progress and

give milestone dates when progress and final reports will be available. Keep in mind that EPA may re-evaluate its position based on the results of health effects studies. We may also have to re-evaluate our position if the diesel vehicle sales fraction increases significantly.

Sincerely yours,

Robert E. Maxwell, Director
Certification Division
Office of Mobile Sources

cc: J. German
C. Gray
P. Lorang
R. Wilson